

| Notice of Allowability | Application No. | Applicant(s) | |
|-------------------------------|------------------------|---------------------|--|
| | 10/053,247 | BERETTA ET AL. | |
| | Examiner | Art Unit | |
| | Patricia M. Bianco | 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to Amendment filed 3/3/05.
2. The allowed claim(s) is/are 2-6, 9, 11, 38 and 44-48.
3. The drawings filed on 15 January 2002 are accepted by the Examiner.
4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some*
 - c) None
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date _____.
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. Notice of References Cited (PTO-892)
2. Notice of Draftperson's Patent Drawing Review (PTO-948)
3. Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 12/04 & 3/05 + 9/05 + 9/07
4. Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. Notice of Informal Patent Application (PTO-152)
6. Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. Examiner's Amendment/Comment
8. Examiner's Statement of Reasons for Allowance
9. Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Claims 20-34 have been cancelled.

Election/Restrictions

This application is in condition for allowance except for the presence of claims 20 to 34, which were claims non-elected without traverse. Accordingly, claims 20-34 have been cancelled (see examiner's amendment above).

Information Disclosure Statement

Applicant filed two Information Disclosure Statements on 12/20/04 and 03/07/05. All references have been considered. However, a majority of the documents listed on the IDS filed 03/07/05 were also listed on the IDS filed 12/20/04 and, therefore, were lined out on the 03/07/05 forms 1449.

Reasons for Allowance

Claims 2-6, 9, 11, 38, & 44-48 are allowed.

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The following is an examiner's statement of reasons for allowance: The subject matter of the independent claims could either not be found or was not suggested in the prior art of record.

With respect to claim 2 & its dependants, the subject matter not found was the combination of a first sealed primary container containing a separation medium that is one of a gel, beads, and a float device, and a sealed secondary container containing an ionic coagulation activator and a transfer device providing fluid communication between the first and second containers in combination with the other elements (or steps) in the claims. With respect to claim 6 & its dependants, the subject matter not found was the combination of a first sealed primary container containing a separation medium that is for separating red blood cells from plasma and having a first pressure, and a sealed secondary container containing an ionic ionic-coagulation activator and having a second pressure lower than the pressure of the first container, and a transfer device comprising a cannula having first and second ends for puncturing the sealed ends of the containers, and wherein the first and second ends are each covered by a retractable elastomeric sleeve in combination with the other elements (or steps) in the claims. With respect to claim 11 & its dependants, the subject matter not found was the combination of a sealed primary container containing a separation medium that is one of a gel, beads, and a float device and having a first pressure, and a sealed secondary container containing an ionic coagulation activator and a second pressure that is less than the first pressure, and a transfer device providing fluid communication between the first and second containers in combination with the other elements (or steps) in the claims.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 30th, 2005

Patricia M Bianco
Primary Examiner
Art Unit 3762

Patricia M. Bianco 5/30/05
PATRICIA BIANCO
PRIMARY EXAMINER